

**Remarks**

1. The Applicant expresses his appreciation to the Examiner for the diligence shown in the examination of this application.
2. A substitute specification is attached as Exhibit A to address changes to the specification in response to the Office Action dated 6/13/2002. The Applicant submits that no new matter was introduced as a result of changes to the substitute specification herein attached. Reconsideration of the application as amended is respectfully requested.
3. The drawings were objected to as failing to comply with 37 CFR 1.84(p)(5) because the drawings:
  - (A) Did not include the reference sign: (136). Reference sign 136 in line has been changed to reference sign 137 (One of the two processing elements of the figure) as supported by the original specification as filed;
  - (B) Did not include (401) in FIG. 4 or (505) in FIG. 5. Reference sign (403) was changed to (401) on page 12, line 23, and reference sign (505) was added after the words "upper end" on line 5 of the substitute specification to correct the errors;
  - (C) The arrow of FIG. 2D was not labeled. Reference sign (246) was added to the arrow and shown in red ink in the substitute drawing 2D attached for Examiner Approval.
4. Edits to correct typographical errors noted by the Examiner were made in the substitute specification and indicated in the "Version With Marked Up Changes" Exception was made in the case of changing "procedures for" on page 1, line 22 and language on lines 21 and 22 of page 10 as the Applicant submits that the original wording is clear.

5. Claims 10 - 12 were amended to more particularly distinguish the invention over the art of record, to overcome claim rejections for indefiniteness under 35 USC section 112, and to correct informalities noted by the Examiner. New claims 17-32 were added. Claims of record are 10-13 and 17-32.

6. Claims 10 and 11 were rejected under 35 U.S.C. section 102(b) as being anticipated by Classon et al. (US 5,567,309). Claims 12 and 13 were rejected under section 103 (a) as being unpatentable over Classon et al as applied to claims 10 and 11, and further in view of Kedar et al. (US 6,083,761) and Donald (US 4,787,971).

7. Classon et al. discloses a self-filtering cap capable filtering and storing liquid. A top cap is placed over a filter cap such that a seal is created between the two caps. Kedar et al. discloses a method and apparatus for transferring and combining reagents. A multiwell plate for handling articles contains wells having a capillary hole adapted to retain articles in the well. Donald discloses a miniaturized column chromatography separation apparatus. The apparatus employs a multi-stage separatory tube, an associated eluent tube, an adapter, a vented cap and a non-vented cap.

**Claims 10 and 20 Recite Novel Physical Features And Structure And Hence Make The Claims Patentable Under Section 102(b).**

8. The Applicant submits that independent claim 10, as amended, and new independent claim 20 recite novel physical features and structure and hence make the claim patentable under section 102(b).

9. Specifically, none of the cited and relied-upon references disclose the steps: positioning a penetrating sample deposit/extraction element above the insert; and inserting the penetrating sample deposit/extraction element through the septum seal, the conical guide, and into the reduced-diameter portion to a depth sufficient to provide axial alignment of the insert and the sample deposit/extraction element.

10. Neither the cited and relied-upon Classon et al., Kedar et al., nor Donald references teach nor suggest these steps as a sampling method utilizing an insert device in a sample vessel. The Classon et al. reference does not teach, nor suggest insertion of needle 86 into well 76 in sufficient depth to provide axial alignment of the needle and the device. Neither Kedar et al. nor Donald teach structure which would allow such steps to be used. Neither does any of the art of record teach the steps recited in these claims.

**The Novel Physical Features Of The Claims Provide New and Unexpected Results And Hence Should Be Considered Unobvious, Making the Claims Patentable Under Section 103.**

11. The Applicant submits that independent claim 10, as amended, and new independent claim 21 provides new and unexpected results and hence should be considered unobvious, making the claim patentable under section 103.

12. Specifically steps of :

positioning a penetrating sample deposit/extraction element above the insert/device; and inserting the penetrating sample deposit/extraction element through the septum seal, the conical guide, and into the reduced-diameter portion to a depth sufficient to provide axial alignment of the insert and the sample deposit/extraction element; provide a means of significantly improving the reliability and repeatability of sample testing by controlling the insertion of the needle and providing alignment of the needle and the insert/device. For example, the combination of the needle guide and the insertion depth of the needle into the reduced-diameter portion sufficient to provide axial alignment of the needle *before* fluid transfer. These steps ensure that the needle position is repeatable and constant with each use. This result, surprisingly, has been found to greatly improve speed and reliability of automated sample testing.

13. The method of Classon et al. begins fluid transfer as soon as the upper cap is inserted into the vessel by the needle housing. In the method of Classon et al., the needle is not aligned by a reduced diameter portion prior to fluid transfer as shown by FIG. 8 of

Classon et al. Neither is the method of sampling of claim 10 and 21 taught or suggested by the cited and relied-upon Kedar et al. or Donald references.

14. Neither does the cited and relied upon references teach, nor suggest, the additional steps and features of the independent claims. For example:

In dependent claims 11 and 26, the positioning and insertion of the needle into the reduced-diameter portion of the insert/device is performed before the insertion of the insert/device into the vessel. Classon et al. neither teach, nor suggest such as method. In fact, neither the method nor structure of Classon et al. allow such the method of the present invention since insertion of cap 12 of Classon et al. into vial 100 occurs before needle 86 enters narrow well 76 as shown in FIG. 8 of Classon et al.

In dependent claims 19 and 27, Classon et al. does not disclose a step of withdrawing the device from the sample vessel by frictional engagement between the septum and needle. In fact, Classon et al. discloses only insertion of the cap *into the vial* by a structure of the sample apparatus (housing 85, collar 106) acting against the *top side* of the septum. Classon et al. does not disclose piercing of the septum by these components, nor use of friction of the needle to permit movement of the device.

In dependent claims 28, 29 and 30 Classon et al. does not disclose, nor suggest, use of frictional engagement of the needle and the septum in moving the insert/device to another processing location (claims 19, 28), withdrawing the device from the vessel and moving to another processing location (claim 29), or withdrawing the device and inserting into another sample vessel (claim 30). The alignment of the needle and insert/device afforded by the method of the present invention allow the reliable and high-speed sampling of this method.

In dependent claims 12 and 13, use of the same needle used for alignment of the device and transfer of fluid to the reduced-volume sample chamber to transfer fluid out of a bottom extraction opening of the sample vessel (claim 12) and also passing through a

processing element (claim 13). Neither the cited and relied-upon Kedar et al., nor the Donald references teach, nor suggest such a use.

In dependent claims 22-25, the step of transferring sample fluid through processing elements (claim 22) including an adsorbent element (claim 23), absorbent element (claim 24), and filter element (claim 25) utilizing the same needle used to align the device with the needle is not taught, nor suggested by, any of the art of record.

### **Unsuggested Combination**

15. Neither the cited and relied upon Classon et al, Kedar et al., nor Donald references contain any suggestion that the disclosed features recited in these remarks be combined.

### **References Take Different Approaches**

16. The Classon et al. reference teaches transfer of a fluid by a cap pressed down in a vessel with a collar. The Kedar et al. reference teaches a capillary hole in a vessel requiring extrinsic forces for transfer. The Donald reference teaches a miniaturized chromatography column. There would be no motivation for one of normal skill in the art to combine the teaching of these disparate references.

### **Multiplicity of Steps Required**

17. The combination, if undertaken, would require a series of separate, awkward combinative steps that are too involved to be considered obvious.

**Combination Still Lacking Novel Features**

18. Even if the references are combined, *the resulting combination would still not result in the present invention*. A combination would not result in a process providing alignment of a needle with a device for insertion in a sample vessel.

**The Cited But Non-Applied References**

19. These subsidiary references have been noted and reviewed, but are submitted to be less relevant than the relied upon references.

**The Dependent Claims Are A-fortiori Patentable**

20. The dependent claims add additional novel features and thus are submitted to be, a-fortiori, patentable.

**Allowance Requested**

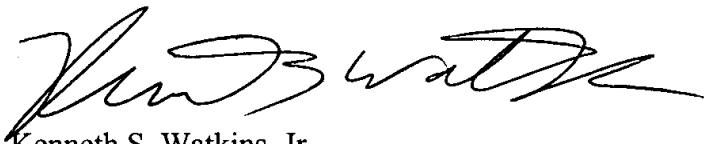
21. For the above reasons, the Applicant's Agent submits that the Sample Collection and Processing Device disclosed and claimed in the present application is not taught by any of the references of record, taken either alone, or in combination. Therefore, allowance of the present application is in order and respectfully requested.

**Request For Constructive Assistance**

22. The undersigned has made a diligent effort to amend the claims of this application so that they define novel structure and render the claimed structure unobvious because it produces new and unexpected results. If for any reason the claims of this application are not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to MEP 707.07(j) and MEP 706.03 (d) in order that this application can be placed in allowable condition as soon as possible and without the need for further proceedings.

23. Attached hereto as Exhibit B is a marked-up version of the changes made to the specification and claims by the current amendment. The attached Exhibit B is captioned **"Version with markings to show changes made"**.

Respectfully Submitted,



Kenneth S. Watkins, Jr.

Reg. No. 37466

Ph. (706) 864-6304

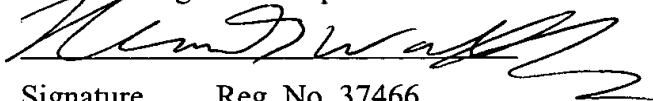
Fax (706) 864-1056

Email [kwatkins@alltel.net](mailto:kwatkins@alltel.net)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C., 20231 on 4/21/2003

Kenneth S. Watkins, Jr.

Name of Registered Representative



Signature      Reg. No. 37466